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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,177	02/11/2002	Robert E. Fischell	APJOHN-10207	1327
23535 7590 08/09/2007 MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			EXAMINER WANG, SHENGJUN	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 08/09/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/072,177	<b>Applicant(s)</b> FISCHELL ET AL.	
	<b>Examiner</b> Shengjun Wang	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 5-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 23-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 11, 2007 has been entered.

#### *Claim Rejections 35 U.S.C. 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. (US 6,726,923), in further view of Berg et al. (USPN 6,068,654).

4. Iyer describes a drug-eluting biodegradable matrix comprising rapamycin for treating anastomosis. (see col. 18-22). The matrix of Iyer is capable of being wrapped around tissues of a human body, because it is perivascularly wrapped around site of interest. The matrix of Iyer is biodegradable and stable (see col. 4, lines 10-col 5, line 40). Iyer encourages the use of other anti-inflammatory such as dexamethasone with rapamycin. (col. 6, lines 55-67). The matrix is particularly useful for wrapping T-shaped vascular vessel joint, wherein the matrix cover the joint as a sleeve. See, particularly, figures 6-13 and column 13, lines 14-20. As it is obvious, a centrally-located hole for placement onto a vessel is taught. See, figures 1-3, and columns 12, lines 7-58.

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5. Iyer et al. do not teach expressly a matrix with annular shape and radial edge.

However, as revealed by Berg et al., T-shaped Joint location of vascular vessel is normally in the shape of a circle, and the connector of the joint is in the shape of annular. See, the figures.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make the matrix of Iyer into an annular wrap with radial edge, as the annular shape would have been a obvious variation of the square shape disclosed by Iyer, particularly in view of the fact that the T-shaped vascular vessel joint is normally in the shape of a circle. As to claims 23 and 24, reciting slit or cut extending toward the edge, it is noted the optimization of the physical shape of the wrap so to accommodate the shape of the vascular vessel being wrapped is a matter of engineering optimization and would have been within the purview of ordinary skill in the art.

6. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. (US 6,726,923), in view of Berg et al. (USPN 6,068,654), and in further view of Casey (USPN 3,902,497).

7. Teachings of Iyer et al. and Berg et al. have been discussed above. Iyer et al. and Berg et al. do not teach expressly the biodegradable material be oxidized regenerated cellulose.

8. However, Casey teaches that oxidized regenerated cellulose is a well-known biodegradable material absorbable in tissues. See, column 2, lines 38-42.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make the matrix of Iyer et al. by using the oxidized

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regenerated cellulose as the biodegradable material because oxidized regenerated cellulose is a well-known biodegradable, bioabsorbable material, and the employment of oxidized regenerated cellulose is seen to be a selection from amongst equally suitable material and as such obvious.

Ex parte Winters 11 USPQ 2<sup>nd</sup> 1387 (at 1388).

***Response to the Arguments***

Applicants' remarks submitted May 11, 2007 have been considered, but are not persuasive.

9. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

10. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teaching, suggestion and motivation are found in the cited references and in the knowledge generally available to one of ordinary skill in the art. Particularly, Berg et al. is cited merely to show that the particular shape of a wrap is known in the art. Further, to optimize the

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shape of a wrap so that the wrap be better fit the tissue being wrapped is deemed within the purview of ordinary skill in the art

The evidence of record shows that the subject matter as claimed is a combination of known components selected for their known properties as surgical wrap and proper shape for fitting the tissue be wrapped. A claim which unites elements with no change in their respective functions to yield a predictable result is not patentable in the absence of secondary considerations.

For over a half century, the [Supreme] Court has held that a "patent for a combination which only unites old elements with no change in their respective functions ...obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152 [87 USPQ 303] (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

*KSR Int'l v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (2007).

No explicit teaching is necessary to have led the skilled worker to the particular components – a surgical wrap and a proper shape for a tissue being wrapped - recited in claims because each was known, or obvious to one of ordinary skill in the art, prompting the skilled worker to have combined them.

As to the arguments that the cited references do not teach all the limitation recited in the claims, particularly, the exactly shapes of the surgical wrap. The examiner note that prior art is not limited just to the references being applied, but including the understanding of one of ordinary skill in the art. The prior art reference(s) need not teach or suggest all the claim limitation. As discussed above, the mere difference in shape over the prior art wrap is not sufficient for establish a prima facie case of unobviousness. The optimization of the shape of a

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wrap to fit a particular shaped tissue, such as T shaped vascular vessel is within the purview of ordinary skilled artisan. One of ordinary skill in the art would have been motivated to make such modification based on the prior art simply by design incentives.

As to the rejections of claims 25-28, applicants argue that Casey only teach the employment of the oxidized regenerated cellulose for gelatin, note question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must considered. In re Lamberti and Konort (CCPA), 192 USPQ 278. It is noted that the particularly biodegradable polymer recited in the claims is a well-known biodegradable material absorbable in tissues. One of ordinary skill in the art would have been able to carry out such a substitution, and the results were reasonable predictable. Further, it is noted the claims merely require the presence of oxidized regenerated cellulose, and do not require oxidized regenerated cellulose as the main component for forming the wrap.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. SHENGJUN WANG  
PRIMARY EXAMINER  
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Primary Examiner  
Art Unit 1617